

WHAT IS CLAIMED IS:

- 1           1. A method for inhibiting hyperplasia at a vascular treatment site, said  
2 method comprising:  
3                 directing vibrational energy at the vascular treatment site, wherein a scaffold  
4 structure has been implanted at said site, said scaffold structure being coated with a  
5 pharmaceutical agent which is released into the site over time, wherein directing vibrational  
6 energy comprises positioning a transducer on a catheter at the vascular treatment site and  
7 driving the transducer to emit the vibrational energy at the same time as the scaffold structure  
8 is implanted.
- 1           2. A method as in claim 1, wherein the vibrational energy is directed at  
2 the site at the time of implantation of the scaffold structure at a frequency and thermal index  
3 which will inhibit an acute phase of the hyperplasia, wherein the pharmaceutical agent is  
4 released over a period of at least one week following implantation to provide a longer term  
5 inhibition.
- 1           3. A method as in claim 2, wherein the vibrational energy does not cause  
2 significant cavitation in a wall of the blood vessel.
- 1           4. A method as in claim 2, wherein the vibrational energy causes a  
2 temperature rise below 10°C in the wall of the blood vessel.
- 1           5. A method as in claim 2, wherein vascular smooth muscle cells at least  
2 mostly remain viable but in a quiescent state in the neointimal layer after exposure to the  
3 vibrational energy.
- 1           6. A method as in claim 2, wherein migration of vascular smooth muscle  
2 cells into the neointimal layer is not substantially inhibited.
- 1           7. A method as in claim 2, wherein viability of vascular smooth muscle  
2 cells in a medial layer of the blood vessel is not significantly inhibited.
- 1           8. A method as in claim 2, wherein the vibrational energy has a frequency  
2 in the range from 20 kHz to 5MHz.

1                   9.       A method as in claim 8, wherein the intensity is in the range from 0.01  
2 W/cm<sup>2</sup> to 100 W/cm<sup>2</sup>.

1                   10.      A method as in claim 9, wherein the frequency and intensity are  
2 selected to produce a mechanical index at the neointimal wall in the range from 0.1 to 50.

1                   11.      A method as in claim 2, wherein the vibrational energy is directed  
2 against the implantation site with a pulse repetition frequency (PRF) in the range from 10 Hz  
3 to 10 kHz.

1                   12.      A method as in claim 2, wherein the energy is directed against the  
2 implantation site with a duty cycle in the range from 0.1 to 100 percent.

1                   13.      A method as in claim 1, wherein the vibrational energy is directed at a  
2 mechanical index selected to effect or promote release of the pharmaceutical agent from the  
3 implanted scaffold structure.

1                   14.      A method as in claim 13, wherein the frequency is in the range from  
2 20 kHz to 5 MHz and the intensity is in the range from 0.01 w/cm<sup>2</sup> to 100 W/cm<sup>2</sup>.

1                   15.      A method as in claim 1, wherein the vibrational energy is directed at a  
2 mechanical index selected to condition the vascular wall to enhance uptake of the  
3 pharmaceutical agent.

1                   16.      A method as in claim 15, wherein the frequency is in the range from  
2 300 kHz to 3 MHz and the intensity is in the range from 0.1 w/cm<sup>2</sup> to 20 W/cm<sup>2</sup>.

1                   17.      A method as in claim 1, further comprising directing vibrational  
2 energy at the vascular treatment site at least one additional time.

1                   18.      A method as in claim 17, wherein vibrational energy is directed at the  
2 vascular treatment site at least once at the time of implanting the scaffold structure and at  
3 least once one day or longer following implantation.

1                   19.      A method as in claim 1, wherein directing vibrational energy  
2 comprises externally generating vibrational energy and directing the vibrational energy  
3 transcutaneously to the vascular treatment site.

1                   20. A method as in claim 19, wherein externally generating the vibrational  
2 energy comprises focusing an externally generated acoustic beam at the vascular treatment  
3 site.

1                   21. A method as in claim 1, wherein the pharmaceutical agent comprises  
2 an agent selected from the group consisting of:

3                   anti-coagulants (heparin, hirudin, GpIIB/IIIA inhibitors), anti-proliferation  
4 agents (paclitaxol, nitric oxide), anti-inflammatory agents (dexamethasone,  
5 methylprednisolone), antibiotics (rapamyacin) and anti-oxidants (probucol).

1                   22. A method as in claim 1, wherein the pharmaceutical agent comprises a  
2 nucleic acid sequence.

1                   23. A method as in claim 22, wherein the nucleic acid sequence comprises  
2 genes expressing VEGF, thymidine kinase, eNOS and antisense oligonucleotides such as c-  
3 myc.

1                   24. A method as in claim 1, wherein the pharmaceutical agent is directly  
2 layered onto the scaffold structure.

1                   25. A method as in claim 1, wherein the pharmaceutical agent is dispersed  
2 in a biodegradable matrix applied to the surface of the scaffold structure.

1                   26. A method as in claim 25, wherein the biodegradable matrix comprises  
2 polylactic acid or polyglycolic acid.